General Assembly

Raised Bill No. 371

February Session, 2000

LCO No. **1668**

Referred to Committee on General Law

Introduced by:
(GL)

An Act Concerning The Classification And Regulation Of Drugs By The Department Of Consumer Protection.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subdivision (49) of section 21a-240 of the general statutes is repealed and the following is substituted in lieu thereof:

(49) "Restricted drugs or substances" are the following substances without limitation and for all purposes: Datura stramonium; hyoscyamus niger; atropa belladonna, or the alkaloids atropine; hyoscyamine; belladonnine; apatropine; or any mixture of these alkaloids such as daturine, or the synthetic homatropine or any salts of these alkaloids, except that any drug or preparation containing any of the above-mentioned substances which is permitted by federal food and drug laws to be sold or dispensed without a prescription or written order shall not be a controlled substance; amyl nitrite; the following volatile substances to the extent that said chemical substances or compounds containing said chemical substances are sold, prescribed, dispensed, compounded, possessed or controlled or delivered or administered to another person with the purpose that said chemical substances shall be breathed, inhaled, sniffed or drunk to

induce a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system: Acetone; benzene; butyl alcohol; butyl nitrate and its salts, isomers, esters, ethers or their salts; cyclohexanone; dichlorodifluoromethane; ether; ethyl acetate; formaldehyde; hexane; isopropanol; methanol; methyl cellosolve acetate; methyl ethyl ketone; methyl isobutyl ketone; nitrous oxide; pentochlorophenol; toluene; toluol; trichloroethane; trichloroethylene; 1,4 butanediol.

Sec. 2. Subsection (k) of section 21a-106 of the general statutes is repealed and the following is substituted in lieu thereof:

(k) If it is a **[**drug sold at retail for use by man and contains any quantity of amidopyrine, barbituric acid, cinchophen, bishydroxycoumarin, dinitrophenol, methylparafynol, thiouracil or thyroid, or any derivative of any of these substances, or (1) is a habit-forming drug to which subsection (d) of this section applies; or (2) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (3) is limited by an effective application under section 21a-111 to use under the professional supervision of a practitioner licensed by law to administer such drug, unless it is sold on a written, oral or electronically-transmitted prescription of a practitioner licensed by law to administer such drug; and its label bears the name and place of business of the seller, the serial number and date of such prescription and the name of such practitioner**]** legend drug, as defined in subdivision (14) of section 20-571, as amended by this act.

Sec. 3. Section 20-617 of the general statutes, as amended by public act 99-49 and section 38 of public act 99-175, is repealed and the following is substituted in lieu thereof:

Each pharmacist shall include on the label of each prescription container: (1) The quantity of prescribed drug placed in such container,

in addition to any other information required by law; and (2) a prominently printed expiration date based on the manufacturer's recommended conditions of use and storage that can be read and understood by the ordinary individual. **[**under customary conditions of purchase, use and storage based on the manufacturer's recommended guidelines. In the absence of data to the contrary, the**]** The expiration date required pursuant to subdivision (2) of this section shall be no later than the expiration date determined by the manufacturer.

Sec. 4. Subsection (l) of section 21a-249 of the general statutes is repealed and the following is substituted in lieu thereof:

(l) Any pharmacy may transfer prescriptions for controlled substances included in schedules III, IV and V to any other pharmacy in accordance with the requirements set forth in **[**21 CFR 1306.26**]** the federal Controlled Substances Act and the regulations promulgated thereunder, as from time to time amended.

Sec. 5. Subdivisions (13) and (14) of section 20-571 of the general statutes, as amended by section 6 of public act 99-175, are repealed and the following is substituted in lieu thereof:

(13) "Legend device" means a device that is required by applicable federal or state law to be dispensed pursuant only to a prescription or is restricted to use by prescribing practitioners only or that, under federal law, is required to bear either of the following legends: (A) **[**"RX ONLY IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT."**]** "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.";

(14) "Legend drug" means a drug that is required by any applicable federal or state law to be dispensed pursuant only to a prescription or

is restricted to use by prescribing practitioners only, or means a drug that, under federal law, is required to bear either of the following legends: (A) **[**"RX ONLY IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT."**]** "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT; or (B) "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG FOR USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN.".

Sec. 6. Section 21a-318 of the general statutes, as amended by section 50 of public act 99-175, is repealed and the following is substituted in lieu thereof:

An application for registration pursuant to this chapter shall be made upon a form provided by the Commissioner of Consumer Protection and shall be accompanied by a fee of **[**twenty-five**]** ten dollars for **[**biennial licensure**]** annual registration, except that a practitioner who obtains such registration pursuant to the practitioner's employment with a municipality, this state or the federal government shall not be required to pay the fee.

Statement of Purpose:

To add the chemical "1,4 butanedioli" to the list of restricted drugs or substances, to provide that a drug is misbranded if it is a legend drug, to revise the requirement for expiration dates on prescription drugs, to revise a reference to federal law, to make technical changes in the definitions of "legend device" and "legend drug" and to revise the controlled substance registration fee.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]